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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,902	11/26/2003	Paul Richard Heaton	HO-P02375US1	2910

26271 7590 05/25/2006

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,902	HEATON ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/26/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 11/26/2003.

Claims 1-19 are pending and included in the prosecution.

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-9 are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: "producing a foodstuff". The claims are directed to method of producing foodstuff, without actual method steps to produce the foodstuff.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-23, 37-41 and 50-51 of copending Application No. 10/282,929. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: the present claims and the copending conflicted

claims are directed to method for treating disorders caused by damage caused by free radical comprising the step of administering to a companion animal a food comprising antioxidants comprising vitamin E, vitamin C, taurine and carotenoids. The disorders claimed by the copending application result from damage by free radicals that cause damage to DNA and consequently damage to different organs and to the immune system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of copending Application No. 10/639,139. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: the present claims and the copending conflicted claims are directed to method for treating disorders caused by damage caused by free radical comprising the step of administering to a companion animal a food comprising antioxidants comprising vitamin E, vitamin C, taurine and carotenoids. The disorders claimed by the copending application result from damage by free radicals that cause damage to DNA and consequently damage to different organs and to the immune

system. The administration of foodstuff comprising vitamin E will inherently increases the plasma level of vitamin E.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-19 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 00/44375 ('375).

WO '375 disclosed method to overcome the oxidative stress in cat or dog by providing foodstuff or supplement having antioxidant elements (abstract; page 2, lines 24-27; page 13, lines 7-23). The foodstuff covers all foodstuff or supplement in any form such as solid, semi-solid or liquid (page 3, lines 12-15). The foodstuff comprises 20 mg/400 kcal vitamin C, 50 IU/400 kcal vitamin E, 200 mg/400 kcal taurine; and

carotenoids including 0.17 mg/400 kcal lutein, 0.03 mg/400 kcal lycopene and 0.01 mg/400 kcal beta-carotene (page 10, line25 till page 11, line 14; claims 1-33).

9. Claims 1, 3-6, 8-11, 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by the article "Antioxidant may improve pet health".

The article disclosed that pet including dogs need antioxidant in their food or as pills to protect pet against oxygen free radicals. The dog will need 80 IU of vitamin E, which is above 25 IU/400 kcal; 50 mg of vitamin C, which is above 10 mg/400 kcal; and 1.5 of beta-carotene, which is above 0.01 mg/400 kcal. See the entire article.

10. Claims 1, 3-6, 8-11, 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by the article "Antioxidant Vitamins in Canine Nutrition".

The article disclosed that the supplemental antioxidants are recommended to canine to protect against damage to cell DNA caused by free radicals. The recommended doses of antioxidants are 80 IU of vitamin E, which is above 25 IU/400 kcal; 50mg of vitamin C, which is above 10 mg/400 kcal; and 4.5 mg beta-carotene, which is above 0.01 mg/400 kcal. See the entire document.

11. Claims 1, 2, 8-13, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by "Dietary antioxidant in cat and dog nutrition" by Harper.

Harper disclosed provision of dietary antioxidants to cat and dogs including vitamin E, vitamin C, carotenoids and taurine because these antioxidants are major

defense against oxidative stress and they protect membrane and cytosolic components against free radical damage. See entire document.

12. Claims 1, 8-11, 13, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 845 216 ('216).

EP '216 disclosed animal feed for horses comprising vitamin E, vitamin C, lutein and beta-carotene (abstract; page 3, lines 50-60; page 7, lines 37, 46-52). The effect of the composition on the DNA damage is inherent.

13. Claims 1, 8-11, 13, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 838 955 ('955).

EP '955 disclosed animal feed for fish, cat and dogs comprising vitamin E, vitamin C, lutein and beta-carotene (abstract; page 4, lines 37-39, 42-45, 55-60; page 6, lines 35-55). The effect of the composition on the DNA damage is inherent.

14. Claims 1, 2, 8-13, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,261,598 ('598).

US '589 discloses animal food formulation comprising antioxidant for cytoprotection, wherein the formulation comprises mixture of beta carotene, lycopene and lutein; and further comprising vitamin E, vitamin C, and taurine (abstract; col.1, lines 27-30, 51-54; col.2, lines 41-46, 53-57, 63). The effect of the composition on the DNA damage is inherent.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 2, 7, 12, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article "Antioxidant may improve pet health" in view of the article "Dietary antioxidant in cat and dog nutrition" by Harper.

The article "Antioxidant may improve pet health" teaches pet including dogs need antioxidant in their food or as pills to protect pet against oxygen free radicals. The dog will need 80 IU of vitamin E, which is above 25 IU/400 kcal; 50 mg of vitamin C, which is

above 10 mg/400 kcal; and 1.5 of beta-carotene, which is above 0.01 mg/400 kcal. See the entire article.

The article does not disclose taurine in composition and its amount.

Harper teaches provision of dietary antioxidants to cat and dogs including vitamin E, vitamin C, carotenoids and taurine because these antioxidants are major defense against oxidative stress and they protect membrane and cytosolic components against free radical damage.

Therefore, it would have been to one having ordinary skill in the art at the time of the invention to provide pet food comprising vitamins E and C, and beta carotene as disclosed by the article "Antioxidant may improve pet health", and further add taurine to the food as disclosed by Harper, motivated by the teaching of Harper that these antioxidants are major defense against oxidative stress and they protect membrane and cytosolic components against free radical damage, with reasonable expectation of having pet food comprising vitamins E and C, beta carotene and taurine that protect cells against damage by free radicals effectively.

The combination of the articles does not teach the amount of taurine. The amount of taurine does not impart patentability to the claims absent evidence to the contrary.

18. Claims 2, 7, 12, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article "Antioxidant Vitamins in Canine Nutrition" in view of "Dietary antioxidant in cat and dog nutrition" by Harper.

The article "Antioxidant Vitamins in Canine Nutrition" teaches that the supplemental antioxidants are recommended to canine to protect against damage to cell DNA caused by free radicals. The recommended doses of antioxidants are 80 IU of vitamin E, which is above 25 IU/400 kcal; 50mg of vitamin C, which is above 10 mg/400 kcal; and 4.5 mg beta-carotene, which is above 0.01 mg/400 kcal. See the entire document.

The article "Antioxidant Vitamins in Canine Nutrition" does not disclose taurine in composition and its amount.

Harper teaches provision of dietary antioxidants to cat and dogs including vitamin E, vitamin C, carotenoids and taurine because these antioxidants are major defense against oxidative stress and they protect membrane and cytosolic components against free radical damage.

Therefore, it would have been to one having ordinary skill in the art at the time of the invention to provide pet food comprising vitamins E and C, and beta carotene as disclosed by the article "Antioxidant Vitamins in Canine Nutrition" and further add taurine to the food as disclosed by Harper, motivated by the teaching of Harper that these antioxidants are major defense against oxidative stress and they protect membrane and cytosolic components against free radical damage, with reasonable expectation of having pet food comprising vitamins E and C, beta carotene and taurine that protect cells against damage by free radicals effectively.

The combination of the articles does not teach the amount of taurine. The amount of taurine does not impart patentability to the claims absent evidence to the contrary.

19. Claims 3-7, 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Dietary antioxidant in cat and dog nutrition" by Harper in view of WO 00/72698 ('698).

Harper teaches provision of dietary antioxidants to cat and dogs including vitamin E, vitamin C, carotenoids and taurine because these antioxidants are major defense against oxidative stress and they protect membrane and cytosolic components against free radical damage. See entire document.

Harper does not teach the amounts of each element of the dietary composition as instantly claimed. Harper does not teach the species of carotenoids as claimed in claims 2 and 13.

WO '698 teaches feed for companion animals to enhance the immune response and improve the overall health of the animal comprising vitamin E and beta carotene (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide foodstuff comprising vitamin E, vitamin C, carotenoids and taurine to protect cell membrane and cytosolic components against free radical damage as disclosed by Harper, and replace carotenoids by lutein or beta carotene as disclosed by WO '698, motivated by the teaching of WO '698 that lutein and

beta carotene enhance the immune response and improve the overall health of the animal, with reasonable expectation of having foodstuff comprising vitamin E, vitamin C, taurine and lutein or beta carotene that has enhanced protective effect for the cells against damage by free radicals with enhanced immune response and improved over all health of the animal.

The combination of the references does not teach the claimed amounts of the ingredients of the food stuff.

The claimed amounts do not impart patentability to the claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

20. Claims 2-7, 12, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 845 216 ('216) in view of "Dietary antioxidant in cat and dog nutrition" by Harper.

EP '216 disclosed animal feed for horses comprising vitamin E, vitamin C, lutein and beta-carotene (abstract; page 3, lines 50-60; page 7, lines 37, 46-52).

EP '216 does not teach the amounts of the ingredients in the foodstuff or the taurine and its amount.

Harper teaches provision of dietary antioxidants to cat and dogs including vitamin E, vitamin C, carotenoids and taurine because these antioxidants are major defense

against oxidative stress and they protect membrane and cytosolic components against free radical damage.

Therefore, it would have been to one having ordinary skill in the art at the time of the invention to provide pet food comprising vitamins E and C, and beta carotene as disclosed by EP '216 and further add taurine to the foodstuff as disclosed by Harper, motivated by the teaching of Harper that these antioxidants are major defense against oxidative stress and they protect membrane and cytosolic components against free radical damage, with reasonable expectation of having pet food comprising vitamins E and C, beta carotene and taurine that protect cells against damage by free radicals effectively.

The combination of the articles does not teach the amount of different ingredient in the foodstuff. The amount of taurine does not impart patentability to the claims absent evidence to the contrary.

21. Claims 2-7, 12, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 838 955 ('955) in view of "Dietary antioxidant in cat and dog nutrition" by Harper.

EP '955 disclosed animal feed for fish, cat and dogs comprising vitamin E, vitamin C, lutein and beta-carotene (abstract; page 4, lines 37-39, 42-45, 55-60; page 6, lines 35-55).

EP '955 does not teach the amounts of different ingredients in the foodstuff or the taurine and its amount.

Harper teaches provision of dietary antioxidants to cat and dogs including vitamin E, vitamin C, carotenoids and taurine because these antioxidants are major defense against oxidative stress and they protect membrane and cytosolic components against free radical damage.

Therefore, it would have been to one having ordinary skill in the art at the time of the invention to provide pet food comprising vitamins E and C, and beta carotene as disclosed by EP '955 and further add taurine to the foodstuff as disclosed by Harper, motivated by the teaching of Harper that these antioxidants are major defense against oxidative stress and they protect membrane and cytosolic components against free radical damage, with reasonable expectation of having pet food comprising vitamins E and C, beta carotene and taurine that protect cells against damage by free radicals effectively.

The combination of the articles does not teach the amount of different ingredient in the foodstuff. The amount of taurine does not impart patentability to the claims absent evidence to the contrary.

22. Claims 3-7, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,261,598 ('598).

US '598 teaches animal food formulation comprising antioxidant for cytoprotection, wherein the formulation comprises mixture of beta carotene, lycopene and lutein; and further comprising vitamin E, vitamin C, and taurine (abstract; col.1, lines 27-30, 51-54; col.2, lines 41-46, 53-57, 63).

US '598 does not teach the amounts of each element of the dietary composition as instantly claimed.

The claimed amounts do not impart patentability to the claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide foodstuff for cytoprotection comprising vitamin E, vitamin C, carotenoids and taurine as disclosed by US '598, and adjust the amount of each ingredient according to the specific need of the animal, with reasonable expectation of having foodstuff containing the optimal amount desired to protect specific animal.

23. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/72698 ('698) in view of "Dietary antioxidant in cat and dog nutrition" by Harper.

WO '698 teaches feed for companion animals to enhance the immune response and improve the overall health of the animal comprising vitamin E and beta carotene (abstract).

WO '698 does not each the feed to comprise vitamin C or taurine and the amounts of each ingredient as instantly claimed.

Harper teaches provision of dietary antioxidants to cat and dogs including vitamin E, vitamin C, carotenoids and taurine because these antioxidants are major defense

against oxidative stress and they protect membrane and cytosolic components against free radical damage.

Therefore, it would have been to one having ordinary skill in the art at the time of the invention to provide pet food comprising vitamins E and beta carotene as disclosed by WO '698 and further add vitamin C and taurine to the food as disclosed by Harper, motivated by the teaching of Harper that these antioxidants are major defense against oxidative stress and they protect membrane and cytosolic components against free radical damage, with reasonable expectation of having pet food comprising vitamins E and C, beta carotene and taurine that protect cells against damage by free radicals effectively.

The combination of the articles does not teach the amount of different ingredient in the foodstuff. The amount of taurine does not impart patentability to the claims absent evidence to the contrary.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis Ghali
Examiner
Art Unit 1615

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